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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/770,517	01/26/2001	Kazuya Mitsuhashi	14879-072001/D1-A0002Y1-U	5879

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EXAMINER

FRONDA, CHRISTIAN L

ART UNIT PAPER NUMBER

1652

DATE MAILED: 03/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
**09/770,517**

Applicant(s)  
**Mitsuhashi et al.**

Examiner  
**Christian L. Fronda**

Art Unit  
**1652**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above, claim(s) 1-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on Jan 26, 2001 is/are a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some\* c) ☐ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 7 and 8 6) ☐ Other:

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## DETAILED ACTION

### *Election/Restriction*

1. Applicant's election without traverse of Group V, claims 11-13, in Paper No. 14 is acknowledged.
2. Claims 11-13 are under consideration in this Office Action.

### *Claim Rejections - 35 U.S.C. § 112, 1st Paragraph*

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:  
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
4. Claims 11-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.  
The claims are directed to any method for producing D-amino acids using any polypeptide of any structure and function. The specification, however, only provides a single representative polypeptide encompassed by these claims: a D-aminoacylase consisting of the amino acid sequence of SEQ ID NO: 2. There is no disclosure of any particular structure to function/activity relationship in the single D-aminoacylase to any other polypeptide of any structure and function. The specification also fails to describe additional representative species of these polypeptides by identifying structural characteristics or properties for which no predictability of structure is apparent. The specification fails to provide a written description of any polypeptide of any structure and function to be used in any method for producing D-amino acids. Thus, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.
5. Claims 11-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for producing D-amino acids using a D-aminoacylase consisting of the amino acid sequence of SEQ ID NO: 2, does not reasonably provide enablement

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for any other embodiment. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized In re Wands [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claims encompass any method for producing D-amino acids using any polypeptide of any structure and function. The specification provides guidance and examples for a method for producing D-amino acids using a D-aminoacylase consisting of the amino acid sequence of SEQ ID NO: 2. While molecular biological techniques and genetic manipulation techniques are known in the prior art and the skill of the artisan are well developed, knowledge regarding the biological function, biological activity, or utility of any polypeptide which can be used in any method for making any D-amino acid is lacking. Thus, searching for the biological function, biological activity, or utility of any polypeptide which can be used in any method for making any D-amino acid is well outside the realm of routine experimentation and predictability in the art of success in determining any polypeptide of any structure and function which can be used in the claimed method is extremely low.

The amount of experimentation to determine the biological function, biological activity, or utility of said polypeptides which can be used in any method for making any D-amino acid is enormous. Such experimentation entails screening for any polypeptide of any structure and function from any biological source and determining whether the polypeptide can be used in any method for making D-amino acids. Since routine experimentation in the art does not include screening vast numbers of polypeptides of any structure and function from any biological source where the expectation of obtaining a desired polypeptide which can be used in any method for making D-amino acids is unpredictable, the Examiner finds that one skilled in the art would require additional guidance, such as information regarding the structure and function of the claimed polypeptide. Without such a guidance, the experimentation left to those skilled in the art is undue.

### *Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph*

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:
- The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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7. Claims 11-13 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: isolating and purifying the produced D-amino acid.

***Claim Rejections - 35 U.S.C. § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claim 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Tokuyama (EP 0896057 A2).

Tokuyama (EP 0896057 A2) teach a D-aminoacylase and method for producing D-amino acids using said D-aminoacylase (see entire publication). Thus, the reference teachings anticipate the claimed invention.

***Conclusion***

10. No claim is allowed

11. The prior art does not teach an isolated D-aminoacylase consisting of SEQ ID NO: 2.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. The fax phone number for this Group is (703)308-0294. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.

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